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BRENDA HERSCHBACH JARRELL  
CHOATE HALL & STEWART  
EXCHANGE PLACE  
53 STATE STREET  
BOSTON, MA 02109-2891

EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary***File Copy*

Application No.

09/478,263

Applicant(s)

JARRELL ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on April 26, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-3 and 5-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### SUBSTITUTE ELECTION OF SPECIES

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

**Please Note:** There is a change in Examiner handling prosecution in the current case from Examiner Bennett Celsa to Jon Epperson.

1. The Response to the Non-Responsive Letter dated April 26, 2002, is acknowledged (Paper No. 15).
2. Applicant's election of species i.e., "peptide synthetases", "peptide synthetase substrates", "polypeptides", and "functionalized polypeptides" is also acknowledged (see Paper No. 15, page 1). However, all previous species elections are withdrawn including those mentioned above.
3. Upon further review of applicants' claims, a substitute election of species was deemed necessary (see below).

#### *Election/Restriction*

4. Upon review of the instant case, the application was deemed to contain claims directed to patentably distinct species of the claimed invention. Election from the following species is required. Note: applicant must elect *one* species from *each* subgroup below. Claim 1 is generic

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Subgroup 1: Species of starter unit (see claim 1)

Applicant must elect, for the purposes of search, a single species of starter unit wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the starter unit. Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. For example, applicant could elect compound 3 in figure 2. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 2: Species of handle (see claim 1)

Applicant must elect, for the purposes of search, a single species of handle wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the handle including all bonds and atoms that are necessary to define its attachment to the solid support unit. Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. For example, applicant could elect the handle indicated in figure 2 for compound 3. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 3: Species of solid support unit (see claim 1)

Applicant must elect, for the purposes of search, a single species of solid support unit wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the solid support unit including all bonds and atoms that are necessary to define its attachment to the handle e.g., "the functionality present on the solid support." Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 4: Species of template structure (see claim 1)

Applicant must elect, for the purposes of search, a single species of template structure. The election should result in a particularly defined core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. For example, applicant could elect any one of the compounds in figure 5. Furthermore, applicant must indicate which claims read on the elected species.

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Subgroup 5: Species of template structure after functionalization (see claim 1 (d))

Applicant must elect, for the purposes of search, a single species of template structure after functionalization. The election should result in a particularly defined core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 6: Species of enzymatic machinery (see claim 1 and 10)

Applicant must elect, for the purposes of search, a single species of enzymatic machinery e.g., polyketide synthase. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 7: Species of unnatural natural product (see claim 2)

Applicant must elect, for the purposes of search, a single species of unnatural natural product. The election should result in a particularly defined core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. For example, applicant could elect any one of the compounds in figure 5. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 8: Species of chemical reaction (see claim 8)

Applicant must elect, for the purposes of search, a single species of chemical reaction e.g., Glaser coupling. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 9: Species of genetically modified enzyme (see claim 9)

Applicant must elect, for the purposes of search, whether the enzymatic machinery includes a genetically modified enzyme i.e., yes or no? If yes, applicant must further elect a single species of genetically modified enzyme (see claim 13). Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 10: Species of antibody recognition element (see claim 14)

Applicant must elect, for the purposes of search, a whether starter unit includes a antibody recognition element i.e., yes or no? If yes, applicant must further elect a single species of antibody recognition element (see claim 14). Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 10: Species of antibody recognition element (see claim 15)

Applicant must elect, for the purposes of search, a whether template structure includes an antibody recognition element i.e., yes or no? If yes, applicant must further elect a single species of antibody recognition element (see claim 15). Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 11: Species of combinatorial techniques (see claim 16)

Applicant must elect, for the purposes of search, a single species of combinatorial technique e.g., parallel synthesis. Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 12: Species of biomolecule (see claim 17)

If Applicant's election includes the attachment of a biomolecule in the functionalization step, applicant must elect, for the purposes of search, a single species of biomolecule e.g., polysaccharide (see claim 18). Furthermore, applicant must indicate which claims read on the elected species.

Subgroup 13: Species of encoding technique (see claim 21)

Applicant must elect, for the purposes of search, a single species of encoding technique e.g., mass spectroscopy. Furthermore, applicant must indicate which claims read on the elected species.

5. **Please note:** applicant must indicate which claims read on the elected species above.

Please avoid typographical errors when indicating claims that read on the elected species (see

Paper No. 15, second to last paragraph, "claims 11-3" should be "claims 1-3").

6. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have

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different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).



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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:00 p.m.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.  
January 1, 2003

BENNETT CELSA  
PRIMARY EXAMINER

